an extrudate having a matrix, and including:

10-50% starch,

0-40% fat or oil,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol

at least about 5% water,

said carrier having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

REMARKS

In the above-identified Office Advisory Action dated September 7, 2001, the Examiner's comments concerning applicant's argument about a non-fat, non-sugar preferred embodiment of the cited Yang have been considered. The Examiner pointed to column 7, line 13 of Yang, stating that xylose, ribose, glucose, mannose, galactose, pertose, dextrose, and maltose were examples of sugars that Yang could use as sweeteners. Further, in the Examiner's report on the interview held, the Examiner stated that a Declaration would be necessary to demonstrate non-obviousness of inclusion of only sucrose as the required sugar to establish criticality of sucrose along with "consisting of" or "consisting essentially of" language. The Examiner has stated that "consisting essentially of" language would be interpreted as "comprising" in the absence of a declaration demonstrating detrimental effects of those ingredients intended to be excluded, citing MPEP 2111.03. Applicant believes that such is not what MPEP 2111.03 states but rather as set

forth therein "the transitional phase consisting essentially of " limits the scope of the claim to the specified materials or steps "and those that do not materially effect the invention" in Re Herz, 537 F2nd 549, 551-52, 190 USPQ 461,463 (CCPA 1976).

Applicant has amended each independent claim 1, 12 and 26, to recite that the sweetener is now sucrose, corn syrup and sorbitol. This is different from the teachings of Yang which may teach other sugars as well as polyhydric alcohol, such as sorbitol, but does not teach sucrose. In fact, Yang teaches away from the use of sucrose as stated in the previous amendment. Yang, is a "substantially fat-free and sucrose free" delivery system. As a result, as now claimed, applicant's invention must have a sweetener that includes sucrose, corn syrup and sorbitol and does not include any sweetener that would constitute a material change in the basic and novel characteristics of the invention. Such is not shown in the prior art of record.

Applicant also includes a declaration by the inventor showing that sucrose is in fact necessary to the invention. Applicant has prepared several formulations, each with a different sugar. All formulations fall within applicant's claimed invention. The conclusion to be drawn from this series of experiments is that the binding power of sucrose is essential to the subject invention. When one uses dextrose the resulting texture is tough, and gets hard over a short period of time. Maltose results in a rubbery texture that also eventually gets hard as a rock. Fructose results in a slimey, sticky, hygroscopic product which will not hold its shape. Finally, the use of lactose results in tough and rubbery non-sweet, gritty product which is hard. On the other hand, the use of sucrose results in a soft pliable, flexible product that holds its shape with a very sweet non-gritty taste The

fact that the sweetener is used as the binder means that with increasing levels of active ingredient, the sweetener becomes very important in its ability to provide strength to the matrix while maintaining texture, mouth feel, sweetness, pliability and a non-slimey appearance in addition to moisture control. Sucrose is the only sweetener with the ability to do all of the above.

Applicant hereby requests reconsideration and reexamination thereof.

With the above amendments and remarks this application is considered ready for allowances and applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below listed number.

Date: December 21, 2001

Respectfully submitted,

WELSH & KATZ, LTD.

By Gerald T. Shekleton

Gerald T. Shekleton
Registration No. 27,466

WELSH & KATZ, LTD.
120 South Riverside Plaza, 22nd Floor
Chicago, Illinois 60606-3913
Telephone: 312/655-1500

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (~~three~~ four times amended) A carrier for the oral administration of an additive selected from the group consisting of pharmaceutical, nutritional supplements, vitamins and minerals, and mixtures thereof to mammals in a discrete dosage form, said carrier comprising:

an extrudate including a matrix having

about 10 to about 50% wt starch,

~~0 to about 40% wt fat or oil,~~

~~about 8 to about 50% wt polyhydric alcohol,~~

a sweetener consisting essentially of sucrose, corn syrup and sorbitol ~~sugar~~,

and

at least about 5% wt water

said carrier having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

12. (~~twice~~thrice amended) A method of making a carrier and additive mixture for use in an oral administration of a therapeutically effective amount of the additive in discrete dosage form, comprising the steps of:

a) forming a matrix and additive admixture by mixing, in a one-step procedure additive,

about 10 to about 50% wt starch,

0 to about 40% wt fat or oil,

~~about 10 to about 50% wt polyhydric alcohol,~~

~~sugar, and~~ a sweetener consisting of sucrose, corn syrup and sorbitol

~~at least about 5%~~ and ~~wt~~ water,

and mixing;

adjusting the relative amounts of polyhydric alcohol and water to control the A_w of said carrier to adjust the level of moisture in the carrier to be a level not inimical to the additive and extruding said carrier and additive to form an extrudate.

26. (~~once~~ twice amended) A carrier for the oral administration of a pharmaceutical additive to mammals in a discrete dosage form, said carrier comprising:

an extrudate having a matrix, and including:

10-50% starch,

0-40% fat or oil,

~~8-50% polyhydric alcohol,~~

a sweetener consisting essentially of sucrose, corn syrup and sorbitol

at least about 5% water,

said carrier having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

1. (four times amended) A carrier for the oral administration of an additive selected from the group consisting of pharmaceutical, nutritional supplements, vitamins and minerals, and mixtures thereof to mammals in a discrete dosage form, said carrier comprising:

an extrudate including a matrix having

about 10 to about 50% wt starch,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol , and

at least about 5% wt water

said carrier having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.

12. (thrice amended) A method of making a carrier and additive mixture for use in an oral administration of a therapeutically effective amount of the additive in discrete dosage form, comprising the steps of:

a) forming a matrix and additive admixture by mixing, in a one-step procedure additive,

about 10 to about 50% wt starch,

0 to about 40% wt fat or oil,

a sweetener consisting of sucrose, corn syrup and sorbitol

and water,

and mixing;

adjusting the relative amounts of polyhydric alcohol and water to control the A_w of said carrier to adjust the level of moisture in the carrier to be a level not inimical to the additive and extruding said carrier and additive to form an extrudate.

26. (twice amended) A carrier for the oral administration of a pharmaceutical additive to mammals in a discrete dosage form, said carrier comprising:

an extrudate having a matrix, and including:

10-50% starch,

0-40% fat or oil,

a sweetener consisting essentially of sucrose, corn syrup and sorbitol

at least about 5% water,

said carrier having an A_w of about 0.60 to about 0.75, and a soft and chewy texture, and said A_w being adjusted to permit an appropriate amount of free water in the presence of the additive.